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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/051,443

04/10/1998

CARIN WIDERSTROM

06275/124001

8003

26161 7590 06/17/2008

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EXAMINER

YU, JUSTINE ROMANG

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

06/17/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

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1 RECORD OF ORAL HEARING  
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3 UNITED STATES PATENT AND TRADEMARK OFFICE  
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5  
6 BEFORE THE BOARD OF PATENT APPEALS  
7 AND INTERFERENCES  
8

9  
10 Ex parte CARIN WIDERSTROM  
11

12  
13 Appeal 2007-4164  
14 Application 09/051,443  
15 Technology Center 3700  
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18 Oral Hearing Held: May 15, 2008  
19  
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21  
22 Before WILLIAM F. PATE, LINDA E. HORNER, JOHN C. KERINS,  
23 Administrative Patent Judges

24  
25 ON BEHALF OF THE APPELLANT:  
26

27  
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34 The above-entitled matter came on for hearing on May 15, 2008, at the U.S.  
35 Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia,  
36 before Timothy J. Atkinson, Jr., Reporter, Free State Reporting, Inc.

P R O C E E D I N G S

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MS. BEAN: Calendar Number 35, Mr. Devoto.

JUDGE PATE: Thank you, Lisa.

MS. BEAN: You're welcome.

JUDGE PATE: Good afternoon, Mr. Devoto.

MR. DEVOTO: Good afternoon.

JUDGE PATE: We've taken an opportunity to familiarize ourselves  
with your application beforehand.

MR. DEVOTO: Great.

JUDGE PATE: So we're ready to listen to your arguments.

MR. DEVOTO: Okay, fantastic. Sorry, I just wanted to get a little bit  
of water here.

JUDGE PATE: Sure.

MR. DEVOTO: So my name is Rob DEVOTO. I'm a patent attorney  
at Fish & Richardson and I'm here today on behalf of my client AstraZenica.  
Hampus Rystedt, who's a colleague of mine, is going to be just -- he also  
represents AstraZenica and he's going to be just watching these proceedings  
as a visitor.

I want to thank you for your time today. And in the interest of being  
as efficient as possible, what I propose that I'd like to do is kind of walk  
through Claim 1 and talk a little bit about the implementation example from  
the spec in the context of Claim 1, and then talk about the rejection,  
specifically, the two pieces of prior art, the two main pieces of prior art that  
were used to reject the claims, which is the Goettenauer German patent and

1 the Gonda U.S. patent, and the reasons why we think that those rejections  
2 should be withdrawn.

3 So with that being said, I understand you've familiarized yourself with the  
4 patent. I would like to walk through it relatively quickly then with you, if  
5 that's okay.

6 So if you look at Claim 1, Claim 1 is directed to a single-use inhaler  
7 for administering medicaments -- bear with me one second; I want to make  
8 sure I have a copy here -- for administering medicaments by inhalation. And  
9 that could be, for example, this inhaler as shown in Figures 3 and 4 of the  
10 application. Before I actually walk through the specific limitations of Claim  
11 1, I would like to just give you a brief overview of this inhaler.

12 So the inhaler's made up of two parts, a top part that's shown here in  
13 Figure 4-10 and a bottom part 12. What you see in the bottom part, 12 --  
14 and when you put the two pieces together you actually get this inhalation  
15 channel that's formed between them. And what you see in the bottom part  
16 12 is, you see two containers, a container 18 -- or a depression container 18  
17 and a container 20. And container 18 could have a certain amount of  
18 medicament, for example, insulin in it; let's say five units of insulin, for  
19 example, in container 18. And in container 20 you may have, for example,  
20 2.5 units of insulin, a less amount maybe; in this case a 50 percent  
21 predetermined portion of it that's less. And the way -- and when you put the  
22 two together, what you see is you actually have these two tapes, 22 and 24.  
23 And these two tapes actually cover, they cover the top of these containers.  
24 And in fact you can best see that in Figure 5A. They actually cover the top  
25 of the container and they kind of bend around the end of the device and they  
26 cover this aperture that's on the bottom of the containers. That's actually

1 showing in Figures 5A and -- really shown in Figure 5A. And what you see  
2 in Figures 5B and C is what happens when you pull one of these tapes off to  
3 uncover one of these containers.

4 So in use, what you see here is -- the disposable inhaler includes a  
5 mouthpiece, 16. It's got an air inlet, 14. You see that in Figure 3. Let's say,  
6 for example, a patient wants to administer to himself  $7\frac{1}{2}$  units of insulin or  
7 maybe the -- wants to use this inhaler to administer some variable amount of  
8 insulin that might vary during the day from  $2\frac{1}{2}$  units to maybe  $7\frac{1}{2}$  units. In  
9 this case, the -- what the patient would do, would selectively remove  
10 difference of these tapes in order to get the correct dose that they require. So  
11 as you can see here, if we assume container 18 has 5 units and container 20  
12 has 2.5 units, the user would be able to administer to himself or herself a  
13 dose that can vary between 2.5 units by removing the tape off the container  
14 20, five units by removing the tape off of container 18, or 7.5 by removing  
15 both tapes off, and could administer that amount of insulin to them.

16 I'd like to make a few observations that I think are important about  
17 this inhaler. First, this inhaler is able to get an increased dosing variability  
18 by having different amounts of insulin in each container. Specifically, with  
19 only two containers, the inhaler is able to dispense three different doses of  
20 insulin. In contrast, if the inhaler had the same amount of insulin in each  
21 container, it would only be able to dispense two different doses with two  
22 containers. So, for example, let's say you've got five insulin in each  
23 container. If it's the same amount, you really can only dispense either 5 or  
24 10. That's all you're limited to with this inhaler.

25 The second observation I'd like to make is that this inhaler is cheap  
26 and simple. And because it's cheap and simple, it's very limited in the

1 manner in which it can provide a variable dose to a patient. The inhaler is  
2 not able to provide a variable dose by selectively dispensing only portions of  
3 the contents of a container. For example, it's not able to take a container like  
4 container 18 that has five units of insulin and dispense only one unit of the  
5 five units. Rather, as I stated previously, the inhaler's only capable of  
6 dispensing all or none of the contents of a given container. Thus, the dosing  
7 variability that this simple and cheap inhaler can provide is not achieved by  
8 varying the amount dispensed from a given container, but it is instead  
9 achieved through an alternative means by having different containers in the  
10 same inhaler contain different dosage amounts and then selecting, to get the  
11 variable dose, a particular combination of containers that are then each  
12 completely dispensed into the inhalation channel upon being selected. So  
13 this method of achieving variability is a cheap and simple alternative to  
14 methods that use more complex, sophisticated, and -- used by more  
15 complex, sophisticated, and expensive inhalers that may have the ability to  
16 dispense less than all of the contents of a given container.

17       So now that I kind of talked a little bit about that, the inhaler, I'd like  
18 to just walk quickly through the limitation of Claim 1, which is one I want to  
19 focus on as being a representative claim. So if you look at Claim 1, it's a  
20 single-use inhaler for administering medicaments by inhalation. That could  
21 be, for example, the inhaler shown in Figure 3, as I mentioned before. The -  
22 - it includes an inhalation channel through which a user may inhale. That  
23 could be the inhalation channel that's formed by putting together plates 10  
24 and 12 in the example shown in Figure 3 and 4. The user may inhale via the  
25 mouthpiece, 16, here. So it has that inhalation channel. A first container  
26 containing a first dose of medicant, such as, for example, the container 18

1 which may contain five units of insulin, for example. A first release means  
2 for releasing such first dose into said inhalation channel, such as, for  
3 example, the tape 22, which may be pulled to expose container 18 to the  
4 inhalation channel. At least one subsidiary container containing a subsidiary  
5 dose of medicament, such as, for example, container 20, which may, for  
6 example, contain 2½ units of insulin, and at least one respective subsidiary  
7 release means for releasing such subsidiary dose into said inhalation  
8 channel. That could, of course, be the tape 24, which may be pulled to  
9 expose the container 20 to the inhalation channel.

10 And then the important limitation -- well, they're all important, but  
11 this is certainly a limitation of note, is this last one which says, said first  
12 release means is independently operable of said at least one subsidiary  
13 release means such that one or more of said first dose and said subsidiary  
14 dose may be released into said inhalation channel at the same time and  
15 subset of variable doses provided. And the subsidiary dose of said at least  
16 one subsidiary container is a predetermined fraction of said first dose that is  
17 less than said first dose. So that limitation means that this structure here  
18 with the two different release means, the release means need to be  
19 independently operable in such a fashion that you can release one of the --  
20 the main dose or the first dose, in this case, or the subsidiary dose, or both at  
21 the same time into the inhalation channel in order to get a variable dose.

22 JUDGE PATE: I don't want to short circuit you here, but could you  
23 go over and talk about the Gonda reference.

24 MR. DEVOTO: I'm more than happy. Goettenauer, it's -- in order to  
25 -- and in fact I was about to get into Goettenauer briefly, only because that's  
26 going to be the bulk of the discussion is what Gonda -- how does Gonda

1 change Goettenauer and what makes sense, given its teaching of how you  
2 would change Goettenauer. In order to understand that, I -- have you --  
3 you're all familiar with Goettenauer? I was going to --

4 JUDGE PATE: Yes, we are.

5 MR. DEVOTO: So the concept in Goettenauer is that you have this  
6 disposable package that is -- it's really a package of blisters, what appear to  
7 be blisters -- since we can only go through the figures -- that are loaded onto  
8 some type of an inhaler chassis as you can see from Figure 6B and Figure  
9 6C. What is acknowledged as being missing from Goettenauer is that there's  
10 no description or suggestion that these containers, like two of these blisters,  
11 for example, one, have different amounts of medicament in them. So the  
12 examiner relies on Gonda to get to that.

13 Now, in order to understand -- there's a very specific section of Gonda  
14 that talks about indices on containers and how the indices can say the  
15 amount of insulin, for example, that's dispensed in each container and how  
16 that's useful because different container -- you know, because you can have  
17 containers having different amounts of insulin in them.

18 JUDGE PATE: Exactly.

19 MR. DEVOTO: In order to understand what that means, I think you  
20 have to look at Gonda in its entirety and how you would use that -- and what  
21 would that teach, what would that lead you to do to Goettenauer. So but in  
22 order to understand that, I really would like to talk about Gonda's inhaler.  
23 I'd like to talk a little bit about it, because I think it's important to the --

24 JUDGE PATE: I think we understand. What I was -- go back to this  
25 part where you said that you could have containers with different doses.

26 MR. DEVOTO: Yes. Yes.



1 JUDGE PATE: And it's your position that those containers with  
2 different doses are on different strips?

3 MR. DEVOTO: I would -- it's our position that the examiner's  
4 reading of that statement -- in fact, if I could, the examiner's reading of that  
5 statement, there are two things that I'd like to say about that statement.

6 JUDGE PATE: Okay.

7 MR. DEVOTO: That when you read Gonda in its entirety, it is our  
8 position that the statement if the containers include different amounts of  
9 insulin does not suggest that a single strip or package of medicament or  
10 medicine or insulin has multiple containers with different amounts of  
11 insulin. Rather, we look at the referenced language from two perspectives:  
12 first, from the perspective of what it fails to teach; and, second, from the  
13 perspective of what it would teach -- what teaches when read in light of the  
14 context of all of Gonda's specification in its entirety.

15 So focusing on the first, per se, what it fails to teach. So the examiner  
16 cites as column 42, lines 26 and 27, which states -- which state the  
17 containers include different amounts of insulin for the proposition that the  
18 container's position within the same medicant strip in Gonda contained  
19 different amounts of insulin. In doing so, he interprets this referenced  
20 section to require that the referenced containers are within the same strip.  
21 And he does this under the guise of referencing the entirety of Gonda,  
22 reading the entirety of Gonda, as stated in the examiner's answer. Yet to  
23 arrive at this interpretation, the examiner is reading only one term based on  
24 the entirety of Gonda, namely, the term containers.

25 You'll find it interesting that we agree with the examiner in his  
26 interpretation of the term container as a structure as being element 2 of --

1 shown in Figure 4 of the inhaler of Gonda, that can be part of a greater  
2 disposable package, 46, like that showing in Figures 4 and 7. We agree that  
3 a container can be part of a greater strip. However, much to the chagrin of  
4 our examiner friend -- forgive me for being verbose there -- this does not  
5 end the inquiry in our mind. In fact, you see, while the container may be  
6 simply defined as part of a greater package, observation of this fact has no  
7 bearing on whether the multiple containers as referenced in column 42 are  
8 located on one or more greater disposable packages. Stated differently, if  
9 each container is part of a greater disposable package, it is quite plausible  
10 that two different containers may be part of two different disposable  
11 packages. So if we end our inquiry here without looking further into Gonda,  
12 it is clear that the cited portion of Gonda may be an attempt by its author to  
13 express any of three different options: one, that the two different containers  
14 -- that two different containers having different amounts of insulin are both  
15 on the same package, as what the examiner might suggest; two, that the two  
16 different containers that have different amounts of insulin are on different  
17 packages with each of the packages only including containers having the  
18 same amount of insulin --

19 JUDGE PATE: Okay.

20 MR. DEVOTO: -- or a combination of these two.

21 JUDGE PATE: Okay. Well, let's go --

22 MR. DEVOTO: What we know is that we don't know which one of  
23 these three --

24 JUDGE PATE: Okay. Let's go --

25 MR. DEVOTO: -- was the intent of the author.

26 JUDGE PATE: Let's go to two or three, option two or three.

1 JUDGE PATE: We were looking at this Claim 1 and we didn't see in  
2 here any requirement that the two containers be on the same strip.

3 MR. DEVOTO: Well, the two containers being on the same strip is  
4 really an artifact of how he's proposing that you modify Goettenauer. The --  
5 he's suggesting that you modify Goettenauer which has this ability to  
6 dispense two blisters, maybe, at the same time. You would modify this strip,  
7 this disposable strip or package based on teachings of Gonda that would  
8 suggest that it would be desirable to better customize the insulin dose to  
9 have different amounts of medicament in the different blisters. So our  
10 contention is that -- so he is focusing -- so in order to have that contention,  
11 he would have to say that what we're loading into Gonda's inhaler is a  
12 disposable package that would have that, that would have the two different --

13 JUDGE PATE: That's what the examiner suggests, but --

14 MR. DEVOTO: Right.

15 JUDGE PATE: -- I'm just going back and saying if they -- if these  
16 two containers don't have to be on the same strip, then Gonda looks like  
17 meets this Claim 102.

18 MR. DEVOTO: Well, it doesn't actually. That's an interesting point.  
19 It doesn't actually because Claim -- because this claim requires that the first  
20 release means and the subsidiary release means be configured or be  
21 operable, independently operable such that you can release the first dose, the  
22 subsidiary dose, or both at the same time. So Gonda does not actually teach  
23 releasing two -- the contents of two containers at the same time into the  
24 inhalation channel. In fact, this kind of goes along with the whole thing that  
25 I was talking about of why our disposable inhaler is interesting. Because  
26 we're doing something -- we're getting a variable dose in a very cheap way.

1 JUDGE PATE: I got you. You don't have to go any further.

2 MR. DEVOTO: Okay.

3 JUDGE PATE: At the same time. I understand.

4 MR. DEVOTO: Yeah, at the same time. So then the question then  
5 becomes, of these three, what makes sense given the context of Gonda, of  
6 these three options that we talked about. And it's our position that it does  
7 not actually make sense, given Gonda's teaching, for you to have a single  
8 strip having multiple different doses in the single strip. We find that our  
9 claim structure of having two different containers having different amounts  
10 of insulin in the same package, which allowed our inhaler to offer a variable  
11 dose, is entirely unnecessary in Gonda's inhaler, because Gonda's inhaler  
12 already has a spring, which you see here, spring 22 in handle 21, that enables  
13 a variable dose to be offered through the more flexible dispensing of  
14 portions of a container. They're not forced to do full container by container  
15 variable dosing like we are in our cheap inhaler. So, for example, if Gonda's  
16 inhaler does not have -- so, for example, Gonda's inhaler does not have to  
17 have a container with five units and another container with only 2.5 units of  
18 insulin in a single package --

19 JUDGE PATE: I keep interrupting you. Let's talk about Claim 10.  
20 I'm satisfied one way or another about Claim 9. I want to talk about Claim  
21 10 now.

22 MR. DEVOTO: Okay. I thought you'd get Claim 10. I certainly  
23 want to --

24 JUDGE PATE: This doesn't have to --

25 MR. DEVOTO: I wanted to spend the bulk of my energy on Claim 1.

26 JUDGE PATE: I understand.

1 MR. DEVOTO: And I think that the same rationality you'll see will  
2 apply to the other rejections of Claim 1 and even 9, actually, because you'll  
3 find that Goettenauer --

4 JUDGE PATE: Right. I'm satisfied with respect to 1 and 9, but --

5 MR. DEVOTO: Great.

6 JUDGE PATE: -- I don't find at the same time where on the same --

7 MR. DEVOTO: Yes.

8 JUDGE PATE: -- strip in 10.

9 MR. DEVOTO: Yes. I thought you'd get to it. All right. So this  
10 one's a little different. Okay. So Claim 10, the argument in Claim 10, what  
11 we contend is that, as you see here, you've got this first container that has a  
12 first dose of this substance and a subsidiary container that contains a  
13 subsidiary dose of this substance, and you selectively open the subsidiary  
14 container and the subsidiary container has a actually predetermined fraction  
15 of the amount of substance in the first container. So now you're -- I guess  
16 you're envisioning looking at Gonda as a 102 on 10, is that kind of what  
17 you're thinking?

18 JUDGE PATE: Well, that's a possibility. Go ahead.

19 MR. DEVOTO: Okay.

20 JUDGE PATE: That -- I admit that rejection's not before you, sir.

21 MR. DEVOTO: Yeah. Well, okay. All right, well, I'll give you my  
22 thoughts --

23 JUDGE PATE: Okay.

24 MR. DEVOTO: -- on it anyways. So if you look at Figure -- so if  
25 you look at how Gonda operates and Gonda's inhaler operates, what you'll  
26 find is that it is able to dispense a portion of the containers as we talked

1 about. The spring could dispense a predetermined, any -- actually they  
2 describe as being any predetermined portion of the container. So,  
3 presumably, you could have a portion that's obviously less than the full  
4 contents of the container. So I'm not sure what you're envisioning, but  
5 maybe you're envisioning that you would dispense a portion of the container  
6 and then wait and then --

7 JUDGE PATE: I'm envisioning Gonda with two strips with  
8 containers of different sizes. You put the first strip in, dispense that  
9 container, take that strip out, put the second strip in, and dispense that  
10 container of a different size. And that way we don't require the containers of  
11 different sizes to be on the same strip and I think that would be within the  
12 scope of Gonda and it might be within the scope of this claim. Unless you  
13 can give me a good argument why it's not --

14 MR. DEVOTO: Yeah. That's certainly not what we meant when we  
15 drafted this claim.

16 JUDGE PATE: Okay.

17 MR. DEVOTO: But there's some validity in what you're saying, I  
18 think, as I'm sure you -- that's why you mentioned it. The only argument  
19 that -- that was actually not the combination that I was thinking of, but that's  
20 actually more creative than I came up with. I would have to revisit that  
21 rejection.

22 JUDGE PATE: Okay.

23 MR. DEVOTO: I -- you may have a point there.

24 JUDGE PATE: I understand.

25 MR. DEVOTO: That's --

1 JUDGE PATE: Exactly. I don't have any more questions. Do you  
2 have any questions?

3 JUDGE KERINS: I just have one. It might be a tangential question.  
4 We go back to Claim 1 and we have an apparatus claim.

5 MR. DEVOTO: Yes.

6 JUDGE KERINS: So the last phrase there refers to the subsidiary  
7 dose being a predetermined fraction of a first dose?

8 MR. DEVOTO: Um-hum.

9 JUDGE KERINS: Is that a positive recitation of there's a dose of  
10 medicament in this apparatus?

11 MR. DEVOTO: Oh, I see what you're -- I think you're -- I think I  
12 should raise -- bring to your attention the fact that it's possible that the  
13 appendix of claims that you're looking at -- and I should have mentioned this  
14 right before I began --

15 JUDGE PATE: I was going to ask you about that also.

16 MR. DEVOTO: Yeah.

17 JUDGE PATE: Go ahead.

18 MR. DEVOTO: The -- unfortunately, due to a clerical error -- I know  
19 in -- basically, what happened is when we filed the appeal brief, which was  
20 quite a long time ago, the appeal brief got bounced because it did not include  
21 some amendments that were done in a previous response. In filing the  
22 response to that bounced appeal brief, we provided a new fresh copy of the  
23 appendix of claims. Unfortunately, we got it wrong. We did not include the  
24 amendments to the claims, that I think are very critical amendments, that  
25 were submitted on the response of March 18, 2002, where we got rid of the  
26 for language. So we have -- and I don't know if you're looking at the one

1 with the for -- first container for containing, might be what you're looking at.  
2 That's not what the currently pending claims are. It's, first container  
3 containing a first dose of medicament, which, of course, changes the  
4 limitations significantly from being a function to being structure. We do  
5 have to have the medicament in it. If we didn't, then you could probably 102  
6 us on Goettenauer.

7 JUDGE PATE: The last thing that we got were the ones that were  
8 filed on January 31st, 2006.

9 MR. DEVOTO: Yes, that's the one that -- those are the ones that we  
10 filed in response to that notice that we received. In fact I --

11 JUDGE KERINS: And our bookmark says those are corrected  
12 claims, so --

13 MR. DEVOTO: They were corrected, but they're not -- they weren't  
14 corrected properly. So what I'm going to be doing is, I'm going to be  
15 submitting the corrected claims today, and what you will see -- with respect  
16 to Claim 1, the only change that you'll see is that in the response -- the  
17 amendment that we filed on March 18, 2002, you'll we eliminated the for  
18 language. And that's important to know, obviously, that we eliminated the  
19 for language. And I'm going to be filing that today. So you will have that.  
20 And I certainly apologize for the confusion over that.

21 JUDGE PATE: Right. And we're not going to tell you how we're  
22 going to handle that. Because we don't do amendments here, so --

23 MR. DEVOTO: Okay. Well, it's --

24 JUDGE PATE: You have to make --



1           MR. DEVOTO: We're not actually amending anything. We're just  
2 giving you the correct set of pending claims that weren't properly put into  
3 the appeal brief.

4           JUDGE PATE: I understand.

5           MR. DEVOTO: I apologize for that. I know that's not --

6           JUDGE PATE: I was going to raise that with you as the last issue.

7           MR. DEVOTO: Oh.

8           JUDGE HORNER: No more questions.

9           JUDGE PATE: Okay. We don't have any further questions. We'll  
10 take this case under advisement.

11          MR. DEVOTO: Thank you so much. I appreciate it.

12          (Whereupon, the proceedings were concluded.)